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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/814,179	03/22/2001	Tae-Wan Kim	0609.4910002/JAG/JUK	8573

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EXAMINER	
LANDSMAN, ROBERT S	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 12/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/814,179	KIM ET AL.	
	Examiner	Art Unit	
	Robert Landsman	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) *10-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Formal Matters

A. The Amendment, filed 10/14/03, has been entered into the record.

B. Claims 1-9 and 41 are pending and are the subject of this Office Action.

C. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Title

A. The objection to the title is withdrawn in view of Applicants' amendment.

3. Claim Objection

A. All claim objections have been withdrawn in view of Applicants' arguments or amendments. The Examiner apologizes for inadvertently rejecting independent claim 41 as failing to further limit a previous claim, as no such claim, in fact, exists.

4. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement

A. Claims 1-9 and 41 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 3-4 of the Office Action dated 5/12/03. Applicants argue that they have provided working examples demonstrating that the claimed invention is effective. Paragraphs 0077-0080 of the captioned application provide that CCE is reduced in presenilin mutants. Applicants have shown that CCE is dramatically potentiated when the biological activities of mutant presenilins are abolished, and that CCE activity is inversely correlated to presenilin-linked y-secretase activity. Applicants argue that the specification does not require the artisan to disclose every species encompassed by their claims. Applicants further argue that it has been confirmed since the present invention that neurodegenerative diseases associated with protein aggregation could have overlapping pathologies, and that a treatment effective for one could be effective for others. Applicants provide Exhibits B and C which teach that aggregates from Alzheimer's and poly-Q diseases may cause neuronal cell death. However, this appears to be only speculation and Applicants have still not enabled the full scope of the claims with regard to identifying agents capable of treating all neurodegenerative diseases "associated with neuronal cell death" – especially in the absence of a definition of "associated with." Regardless, though the art may speculate that aggregates may be involved in cell death, the specification does not provide any guidance or working

examples of the effect of measuring CCE on any other neurodegenerative diseases other than Alzheimer's. Applicants also state that the claims are directed to a method for identifying an agent capable of treating a neurodegenerative disease associated with amyloid aggregation or neuronal cell death, not a method for treating a neurodegenerative disease. However, these are 'reach through' claims and, therefore, Applicants claims do need to be enabled for compounds which treat the claimed neurodegenerative diseases. If Applicants do not intend for the identified compounds to treat neurodegenerative diseases, then the claims should not recite this limitation, and should simply be drawn to a screening method. As stands, Applicants have only provided guidance and working examples of compounds which affect CCE in SY5Y cells. (that mutant presenilins mediate downregulation of CCE, and that decreased CCE results in increased production of the protein which aggregates and forms senile plaques in Alzheimer's disease. They have also shown that abolishing the biological activities of mutant presenilins results in an increase of CCE. Therefore, it would not be predictable that diseases other than Alzheimer's could be treated, nor is it even predictable that Alzheimer's, itself, could be treated since Applicants have not provided a nexus that the identification of compounds which are active in vitro is indicative of an in vivo treatment.

In summary, the breadth of the claims is excessive with regard to Applicants claiming methods of identifying agents which can treat any neurodegenerative diseases associated with amyloid aggregation or neuronal cell death. Applicants have only provided guidance and working examples of how to identify agents which mediate CCE in SY5Y cells as it pertains to Alzheimer's plaques. It is not predictable that diseases other than Alzheimer's could be treated, nor is it even predictable that Alzheimer's, itself, could be treated since the specification only discloses in vitro assays to measure CCE. For these reasons, the Examiner maintains that undue experimentation is required to practice the invention as claimed.

5. Claim Rejections - 35 USC § 112, first paragraph – new matter

A. Claims 1-9 and 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants have added the limitation "neuronal cell death" to independent claim 1. However, the Examiner cannot find support for methods of screening compounds which are able to treat diseases associated with neuronal cell death. **This is a new matter rejection.**

6. Claim Rejections - 35 USC § 112, second paragraph

A. The rejection of claims 1-9 and 41 under 35 USC 112, second paragraph, has been withdrawn in view of Applicants' amendments to the claims to recite "capable of."

B. Claims 1-9 and 41 are confusing since the metes and bounds of "associated with" are not defined. It is not clear which diseases are encompassed by the claims.

7. Claim Rejections - 35 USC § 102

A. Claims 1, 9 and 41 remain rejected under 35 USC 102 as being anticipated by Birnbaumer et al. (U.S. Patent No. 5,932,741) for the reasons already of record on page 5 of the Office Action dated 5/12/03. Applicants argue that the cited document does not teach identifying an agent capable of treating a neurodegenerative disease associated with amyloid aggregation or neuronal cell death as required by claims 1 and 41. Claim 9 depends from claim 1, and therefore "shall be construed to include all the limitations of the claim incorporated by reference." 37 C.F.R. 1.75 (c).

This argument has been considered, but is not deemed persuasive. The fact that the agent identified is capable of treating a neurodegenerative disease is an intended use and does not have any patentable weight. One way to look at this is to consider two artisans side by side. One performing the present method and the other performing the method of Birnbaumer. Regardless of the intended use of the compounds identified by each of the artisans, both procedures would appear (and, if fact, be) identical to the onlooker.

B. Claim 1 remains rejected under 35 USC 102 as being anticipated by Birnbaumer et al. (U.S. Patent No. 5,538,983) and by Berridge (Biochem J.) for the reasons already of record on pages 5-6 of the Office Action dated 5/12/03. Applicants argue that the cited document does not teach identifying an agent capable of treating a neurodegenerative disease associated with amyloid aggregation or neuronal cell death as required by claims 1.

This argument has been considered, but is not deemed persuasive. The fact that the agent identified is capable of treating a neurodegenerative disease is an intended use and does not have any patentable weight. One way to look at this is to consider two artisans side by side. One performing the present method and the other performing the method of Birnbaumer. Regardless of the intended use of the compounds identified by each of the artisans, both procedures would appear (and, if fact, be) identical to the onlooker.

C. Claims 1, 9 and 41 remain rejected under 35 USC 102 as being anticipated by Birnbaumer et al. (PNAS 93) for the reasons already of record on page 5 of the Office Action dated 5/12/03. Applicants argue that the cited document does not teach identifying an agent capable of treating a neurodegenerative disease associated with amyloid aggregation or neuronal cell death as required by claims 1 and 41. Claim 9 depends from claim 1, and therefore "shall be construed to include all the limitations of the claim incorporated by reference." 37 C.F.R. 1.75 (c).

This argument has been considered, but is not deemed persuasive. The fact that the agent identified is capable of treating a neurodegenerative disease is an intended use and does not have any patentable weight. One way to look at this is to consider two artisans side by side. One performing the present method and the other performing the method of Birnbaumer. Regardless of the intended use of the compounds identified by each of the artisans, both procedures would appear (and, if fact, be) identical to the onlooker.

8. Claim Rejections - 35 USC § 103

A. All rejections under 35 USC 103 have been withdrawn in view of the submission of a Declaration under 37 CFR 1.132 by Dr. Tae-Wan Kim, Dr. Rudolph E. Tanzi, and Andrew S. Yoo, stating that the Kim et al. abstract was co-authored by all of, and none other than, the inventors named in the captioned application, and that the abstract is a description of their own work.

9. Conclusion

A. No claim is allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
December 17, 2003

Gary L. Kunz

GARY KUNZ
SUPERVISORY PATENT EXAMINER
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